1101

ACTION SUMMARY SHEET

For use of this form, see OTSG Reg 21-51; the proponent agency is the OTSG

SUBJECT Command Policy 2005-02, Policy for the Adherence to Good Clinical Practices During FDA Regulated Clinical Research Activities

SUSPENSE DATE

DATE 26 Jan 05

SUMMARY OF ACTION : (Briefly describe purpose, discussion/background and recommendation for the action.)

1. Purpose: To establish a policy that reaffirms the unified standards by which this Command conducts its FDA regulated clinical research activities. Compliance with the standards listed in the references assures that the rights, safety, and well-being of the trial subjects are the primary focus in conducting research within this Command.

2. Discussion/Background: Within the Command there is a well defined path with associated decision gates (Scientific Review Committee, Human Use Committee, and HSRRB) that a protocol plan goes through to obtain permission to conduct a clinical study. Once the final approval stage is reached and permission to begin enrollment of volunteers into the clinical study is obtained the well defined Command path of human subjects protection ends. This policy clearly defines the expectations that the investigator and all those involved in the product development process are expected to adhere to.

This policy was drafted by QMO, staffed to the Quality Working Group members appointed by their respective Commanders (USAMMDA, WRAIR, ISR, RIID, AFRIMS and USAMRU-K), agreed upon, and then staffed to the Commanders of those organizations. All comments received were addressed.

3. Recommendation: That MG Martinez-Lopez sign the enclosed memorandum for the approval and implementation of this policy as it applies to our subordinate units.

COORDINATIONS *(Continue on reverse if necessary)*

OFFICE	NAME	INITI	DATE
MCMR-ZB-	M. Burman	MCB	1/27/05
MCMR-ZB-	W. Howell		2/4/05
MCMR-ZB-	COL Vaughn	DV	2/7/05
MCMR-SGS	MAJ Blount	MB	11 FEB 05
MCMR-ZC	COL Deutsch		22 Feb
MCMR-ZB	COL Romano		25 Feb 05
MCMR-ZA	MG Martinez-Lopez		1 MAR
MCMR-ZB	M. Burman		

REVIEWS/APPROVALS

	NAME	INIT	DATE
BR CH			
DIV CH			
DIR/OFC CH			
ASST EXEC			
EXEC			
DSG			
TSG			
SACO			
DISPATCHED			

TYPE NAME AND GRADE OF ACTION OFFICER/PHONE NUMBER /OFFICE SYMBOL

Lori Walton, DI-IV, DSN 343-6978, MCMR-ZB-QM

SIGNATURE

SACO COMMENTS:

OTSG Form 337-E
June 1992

Previous editions are obsolete

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPLY TO
ATTENTION OF

MCMR-ZB-QM

14 MAR 2005

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Command Policy 2005-02, Policy for the Adherence to Good Clinical Practices During FDA Regulated Clinical Research Activities.

1. References.

a. 21 Code of Federal Regulations (CFR) Part 11, Electronic Records; electronic signatures.

b. 21 CFR Part 50, Protection of Human Subjects.

c. 21 CFR Part 56, Institutional Review Boards.

d. 21 CFR 312, Investigational New Drug Application.

e. International Conference on Harmonization (ICH) Guidelines E6, Good Clinical Practice: Consolidated Guidance.

f. ICH Guideline E8, General Considerations for Clinical Trials.

g. AR 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule 1 Controlled Substances, 31 July 2002 (draft).

h. AR 40-38, Clinical Investigation Program, 1 September 1989.

i. AR 70-25, Use of Volunteers as Subjects of Research, 25 January 1990.

2. Purpose. This policy reaffirms the unified standards by which this Command conducts its FDA regulated clinical research activities. Compliance with the standards listed in the references assures that the rights, safety, and well-being of the trial subjects are the primary focus in conducting research within this Command.

3. Definitions. These definitions are taken directly from Reference e, Section 1. Glossary.

a. Clinical Trial/Study. Any investigation with a human subject intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. Note that investigational products may be medical devices (including diagnostic devices). The terms clinical study and clinical trial are synonymous.

b. Good Clinical Practice (GCP). A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

c. Institutional Review Board. An independent body constituted of medical, scientific, and nonscientific members whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by among other things reviewing, approving, and providing continuing review of trials, of protocols, and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

d. Informed consent. A process by which a subject voluntarily documents his or her willingness to participate in a particular trial after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is initially documented by means of a written, signed, and dated informed consent form.

e. Investigational Product. A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This may include a product with marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form or when used for an unapproved indication or when used to gain further information about an approved use. In some cases the investigational product may be a device.

f. Protocol. A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial but these could be provided in other protocol referenced documents. Throughout this policy the term protocol refers to protocol and protocol amendments.

g. Subject/Trial Subject. An individual who volunteers to participate in a clinical trial.

h. Well-being (of the trial subjects). The physical and mental health of the subjects participating in a clinical trial.

4. Policy.

a. All FDA regulated investigations involving human subjects in which The Surgeon General is the Sponsor will be conducted in accordance with the principles of Good Clinical Practice.

b. There are five major areas within GCP that need to be addressed prior to and during the conduct of a clinical trial:

(1) For subjects who participate in the research effort;

(a) Estimated risks and inconveniences are evaluated against predicted benefits and the predicted benefits substantiate the risk.

(b) The individual is considered first before the science or society. There may be no benefit to the individual in some cases.

(c) The individual gives his informed consent freely and without influence.

(d) The individual is assured of the confidentiality of his records during participation of the research effort and after completion of the research effort within the limits of relevant regulations.

(e) Only qualified health care providers make medical decisions or provide medical care to the research subject.

(2) In the planning and execution of a clinical trial;

(a) Estimated risks and inconveniences are evaluated against predicted benefits and the predicted benefits substantiate the risk.

(b) The clinical trial is scientifically sound and the procedures, analysis, and data collection forms are clearly detailed.

(c) The clinical trial has undergone appropriate review and approval from an Institutional Review Board.

(d) The information gained from clinical trial conduct is recorded, stored, and handled in a manner to assure accurate reporting, interpretation, and verification.

(3) For the investigational product used in the clinical trial:

(a) Estimated risks and inconveniences are evaluated against predicted benefits and the predicted benefits substantiate the risk.

(b) There is appropriate non-clinical and clinical information on the investigational product adequate to support the clinical trial being conducted.

(c) The investigational product is manufactured, handled, and stored in accordance with applicable good manufacturing processes.

(d) The investigational product is used in accordance with an approved clinical protocol.

(4) Education and Training.

(a) Study personnel have the appropriate education pertinent to their responsibilities in the conduct of the clinical trial.

(b) Study personnel have the appropriate documented training pertinent to their responsibilities in the conduct of the clinical trial.

(5) Quality. There are systems developed, implemented, and examined to assure the quality of every aspect associated with a clinical trial.

5. This policy will continue in effect until rescinded or superceded.

LESTER MARTINEZ-LOPEZ
Major General, MC
Commanding

DISTRIBUTION:
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